2-Phenyl Ethyl Propionate, Eugenol, Geraniol, and (R,Z)-5-(1-Decenyl)dihydro-2(3H)-furanone

PC Code: 102601; 102701; 597501; 116501

Science review: chemistry, mammalian toxicity and non-target organisms.
DP Number(s): 424181 & 424182
EPA Reg. or File Symbol No: 51934-2 & 51934-6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLUTION PREVENTION/OFFICE OF PESTICIDE PROGRAMS

MEMORANDUM

DATE: Dec. 31, 2014

SUBJECT: Science review for a formulation amendment to add unregistered sources of active ingredients to registered products Trece Japanese Beetle Bait II and Japanese Beetle Trap, containing 22.25 % w/w Eugenol, 9.50 % w/w Geraniol, 9.50 % w/w 2-PEP as floral lure, and 0.133 % w/w (R,Z)-5-(1-Decenyl)dihydro-2(3H)-furanone as sex lure in the products.

Decision Number:	495007 & 495009
DP Number:	424181 & 424182
EPA File Symbol Number:	51934-2 and 51934-6
Chemical Class:	Biochemical
PC Code:	102601; 102701; 597501; 116501.
CAS Number:	122-70-3; 97-53-0; 106-24-1; 64726-91-6
Active Ingredients:	2-Phenyl Ethyl Propionate; Eugenol; Geraniol, and (R,Z)-5-(1-Decenyl)dihydro-2(3H)-furanone
Tolerance Exemptions:	Non-food. (40 CFR §180.1251 Geraniol)
MRID Numbers:	494485-01, 494485-02 & 494485-03.

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ACTION REQUESTED

Trece, Inc. is amending the formulation of currently registered products, Japanese Beetle Bait II (EPA Reg. No. 51934-2) and Trece Japanese Beetle Trap (EPA Reg. No. 51934-6), by adding new unregistered sources of active ingredients, 2-Phenyl Ethyl Propionate, Eugenol, and Geraniol; updating the company name and address of the supplier of Furanone Japanese Beetle attractant, and changing the suppliers of inert ingredients in both products. In support of this action, the registrant has submitted revised basic CSFs for both products, signed and dated August 6, 2014, and Preliminary (5 batch) analysis for each active ingredient, Eugenol, Geraniol, and Phenyl Ethyl Propionate, in MRIDs 494485-01 494485-02 and 494485-03, respectively.

RECOMMENDATIONS AND CONCLUSIONS

Product chemistry: Unacceptable.

1. The following deficiencies (1 thru 3) are identified in the submitted data Matrix:

   a. Cited studies in MRIDs 425071-01 and 426302-01 are not found in the Agency's data base. Product Identity and Composition / Manufacturing Process, and Formation of Impurities in cited MRIDs 446010-01 and 450400-01 do not address any of the active ingredients, 2-Phenyl Ethyl Propionate, Eugenol, and Geraniol, from unregistered sources. These cited MRIDs correspond to end-use product Japanese Beetle Combo Bait and active ingredient Furanone, respectively.

   b. Cited MRDs 425071-01; 425071-03, and 425010-02 are not found in the Agency data base.

   c. The same information is repeated in all 3 data matrixes submitted for each active ingredient supplied from an unregistered source.

2. The following product chemistry data requirements, 880.1100; 880.1200, and 880.1400, are not satisfied according to 40 CFR §158.2030. These product specific data requirements need to be satisfied for active ingredients supplied from EPA-unregistered sources. "*Information must be submitted for the current production process for each active ingredient that is not derived from an EPA-registered product*," (40 CFR § 158.330) (These data should be provided to the registrant by the EPA-unregistered supplier of active ingredients listed on the CSF, [redacted]

880.1100 *Product Identity and Composition* in accordance with §158.320 (a)(2) from (i) to (v).

880.1200 *Description of Materials used to produce the Product (Starting Materials)* in accordance with 40 CFR § 158.325 (b) (2) from (i) to (ii) (A) thru (C); *Description of Production* in accordance with 40 CFR § 158.330 (a) thru (b)(8), and *Description of Formulation Process* in accordance with 40 CFR § 158.335.

880.1400 *Discussion of Formation of Impurities* in accordance with 40 CFR §158.340.

Mammalian Toxicity: Unacceptable, due to the following deficiencies (from 1 to 3 below):

1. There is no appropriate cited data for **acute oral, acute dermal toxicity, primary eye irritation, primary dermal irritation, skin sensitization, 90-days oral, 90-days dermal, 90-days inhalation, *In Vitro* mammalian cell assay, and prenatal development listed on the data matrix**. These data requirements are addressed with footnotes, which are insufficient. **The registrant needs to address these data requirement either with applicable data or with scientific rationale** justifying why additional studies are not needed.

2. Cited MRID 450879-01 doesn't correspond to acute inhalation toxicity study for any of the proposed active ingredients, 2-Phenyl Ethyl Propionate, Eugenol, and Geraniol.

In addition,

3. According to cited document, *Preliminary Workplan and Summary Document for registration Review of 2-Phenethyl propionate (2-PEP) (PC Code: 102601) (September 2010) Docket ID: EPA-HQ-OPP-2010-0714. Case 3110*, there are data gaps for this active ingredient that need to be addressed. Specifically, **the registrant needs to satisfy the following data requirements for 2-Phenethyl propionate (2-PEP):**

870.3100-90 days oral;
870.3250-90 days dermal, and
870.3465-90 days inhalation.

All these data requirements are addressed for active ingredients Eugenol and Geraniol in referenced document, *Vegetable and Flower Oils Summary Document Registration Review. (March 2010) Docket ID: EPA-HQ_OPP-2009-0904. Case 8201. Case 8201.*

Non-target Organisms: Unacceptable due to the following deficiencies:

1. No Non-target organisms' data requirements are listed on data matrixes for any of the products containing the proposed active ingredients, 2-Phenyl Ethyl Propionate, Eugenol, and

Geraniol. The registrant needs to revise the data Matrix and re-submit amended forms with the correct information.

2. Data on Non-target organisms are required for registration of products containing new active ingredients or active ingredients supplied from unregistered sources. These data requirements should be individually addressed for each proposed active ingredient in the product according to 40 CFR § 158.2060.

3. According to cited document Preliminary Workplan and Summary Document for registration Review of **2-Phenethyl propionate (2-PEP)** (PC Code: 102601) (September 2010) Docket ID: EPA-HQ-OPP-2010-0714. Case 3110**,** the following data needs are anticipated for 2-PEP: acute and subchronic reproduction, field studies, and effect on non-target organisms. Specifically, the existing data gaps for 2-Phenethyl propionate (2-PEP) are:

850.2100-Avian Acute oral;
850.2200- Avian Acute Dietary;
850.1075-Fish Acute toxicity;
850.1010-Aquatic invertebrate acute toxicity;
880.4350-Non-target Insect testing, and
850.4225; 850.4300; 850.4450 - Non-target plants;

All these data requirements are addressed for active ingredients Eugenol and Geraniol in referenced document, *Vegetable and Flower Oils Summary Document Registration Review. (March 2010) Docket ID: EPA-HQ_OPP-2009-0904. Case 8201. Case 8201.*

Product performance: N/A

STUDY SUMMARY

Preliminary Workplan and Summary Document for registration Review of 2-Phenethyl propionate (2-PEP) (PC Code: 102601) (September 2010) Docket ID: EPA-HQ-OPP-2010-0714. Case 3110.

Product chemistry information for 2-PEP is complete and satisfies current data requirement. For Human Health Risk Assessment, the data on record is deficient; 90-day oral, dermal and inhalation data requirements have not been addressed. All other data requirements are satisfied. Environmental Fate and Ecological Risk Assessment information for products containing 2-PEP as insect lures in pressurized liquid, granular, pellet/tablet, dust solutions ready to use, and emulsified concentrate products is incomplete for lack of Avian, Aquatic, Insect, and Plant toxicity data. The following data needs are anticipated: acute and subchronic reproduction, field studies, and effect on non-target organisms. Specifically, the existing data gaps are:

870.3100-90 days oral;
870.3250-90 days dermal;
870.3465-90 days inhalation;
850.2100-Avian Acute oral;
850.2200- Avian Acute Dietary;
850.1075-Fish Acute toxicity;
850.1010-Aquatic invertebrate acute toxicity;
880.4350-Non-target Insect testing, and
850.4225; 850.4300; 850.4450 - Non-target plants;

Vegetable and Flower Oils Summary Document Registration Review. (March 2010) Docket ID: EPA-HQ_OPP-2009-0904. Case 8201. Case 8201.

This document covers 7 active ingredients, including Eugenol and Geraniol. An exemption from the requirement of a tolerance is established as per 40 CFR §180.1251. No data gaps exist at the moment.

MRID 494485-01, *Eugenol. Preliminary Analysis of a Test Substance (5 Batch Analysis).*

The study was designed to determine the concentrations and purity of Eugenol in 5 batches; each batch was sampled 3 times using liquid chromatography/mass spectrometry (HPLC/MS) and Ultra violet visible spectrometry (UV/Vis). The method was validated for accuracy and precision, detection and quantification of limits. UV/Vis Spectrometry was used for active ingredient identification. Mean percent concentration of Eugenol in all samples was 99.5 % purity.

MRID 494485-01, *Geraniol. Preliminary Analysis of a Test Substance (5 Batch Analysis).*

The study was designed to determine the concentrations and purity of Geraniol in 5 batches; each batch was sampled 3 times using gas chromatography/mass spectrometry (GC/MS). The method was validated for accuracy and precision, detection and quantification of limits. Mean percent concentration of Geraniol in all samples was 99.5 % purity.

MRID 494485-03, *Phenyl Ethyl Propionate. Preliminary Analysis of a Test Substance (5 Batch Analysis).*

The study was designed to determine the concentrations and purity of Phenyl Ethyl Propionate in 5 batches; each batch was sampled 3 times using gas chromatography/mass spectrometry (GC/MS). The method was validated for accuracy and precision, detection and quantification of limits. Mean percent concentration of Phenyl Ethyl Propionate in all samples was 99.8 % purity.

cc: Clara Fuentes, Gina Burnet, BPPD Chron File, IHAD/ARS, FT, PY-S: Dec. 31, 2014